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| 10/566,785 | 01/12/2007 | Jacques-Philippe Moulinoux | U16.12-0006 | 7755 |

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| EXAMINER | |
|---|---|
| KLINKEL, KORTNEY L | |

| ART UNIT | PAPER NUMBER |
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| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/566,785 | MOULINOUX ET AL. | |
| | Examiner | Art Unit | |
| | Kortney L. Klinkel | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1 and 13-32* is/are pending in the application.

4a) Of the above claim(s) *17-22, 28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-16,23-27,29,31 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Claims*

Claims 1, and 13-32 are pending in the instant Office action. Claims 2-12 stand canceled.

### *Election/Restriction*

Applicant's election without traverse of the species of composition having no inhibitor or intercellular synthesis or polyamines, no antibiotic and no vitamins as well as the syndrome or pathology in which the NR2-B sub-unit of the N-methyl-D-aspartate (NMDA) receptor is involved in the reply filed on 9/8/2009 is acknowledged. Claims 1, 13-16, 23-27, 29 and 31-32 encompass the elected species.

Claims 17-22, 28 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/8/2009.

### *Information Disclosure Statement*

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a

separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Acknowledgement is made of applicant's submitting an information disclosure statement on 1/12/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

### *Foreign Priority*

Acknowledgement is made of applicant's foreign priority claim to French patent application serial number 03/09480 filed 7/31/2003. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Specification*

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### *Claim Rejections - 35 USC § 112 2nd Paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 13-15, 27, 29 and 31-32 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13-15 and thereby dependent claims 31-32 do not provide a positive definition of the subject matter for which patent protection is sought. These claims merely indicate what the composition must not contain. This fact leaves the claims open to countless possible food compositions to be administered. The metes and bounds of the subject matter sought for protection is completely unclear.

Claims 13-15 list the negative limitations of the amounts of the various polyamines in the following way: less than about X picomoles/g. The metes and bounds of these negative limitations are unclear. There is no clear upper boundary conveyed by the claims. The phrase “less than” requires the amount to be less than X but the word "about” includes values larger than X. The two phrases contradict one another. Additionally, there is no clear definition of the word “about” in the instant specification so it is also unclear how far reaching the term “about” truly is.

Claims 27 and 29 recite the limitation “sufficient quantities of vitamins, minerals and electrolytes to satisfy the daily nutritional needs of a human being.” It is unclear what quantities of vitamins, minerals and electrolytes are required by these claims. As such, the metes and bounds of these claims are unclear.

Claims 14 and 15 contain broad limitations followed by more narrow limitations due to the word "preferably". A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is

considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 14 and 15 recite the broad recitation “less than about 400” and “less than about 100” respectively, and the claims also recite “preferably less than about 200 picomoles/g of polyamine” and “preferably less than about 50 picomoles/g….cadaverine” respectively, which is the narrower statement of the range/limitation.

### ***Claim Rejections - 35 USC § 112 1st Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 13-15 do not provide a positive definition of the subject matter for which patent protection is sought. These claims merely indicate what the composition must not contain. This fact leaves the claims open to countless possible food compositions to be administered. Applicant has not described these compositions by structure or function to suggest that they were in possession of the full scope encompassed by the claims. In its most generic sense, page 12 of the instant specification describes the composition to be administered as containing preferably 1 to 10 g of polyamine, between 75 and 500 g of glucides, between 20 and 185 g of lipids and between 20 and 225 g of proteins and a sufficient quantity of vatamins, minerals and electrolytes, see also claim 16 which lists these ingredients in terms of weight percents.

Regarding the requirement for adequate written description of chemical entities, Applicant's attention is directed to the MPEP §2163. In particular, *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089, 118 S. Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications under the 35 U.S.C. 112.I "Written Description" Requirement

("Guidelines"), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia*, "functional characteristics when coupled with a known or disclosed correlation between function and structure..." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 316, 1324-25 (Fed. Cir. 2002) (quoting *Guidelines*, 66 Fed. Reg. at 1106 (emphasis added)). Moreover, although *Eli Lilly* and *Enzo* were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. *Univ. of Rochester v. G.D. Searle & Co.*, 249 Supp. 2d 216, 225 (W.D.N.Y. 2003).

Applicants describe no other composition for human consumption that might be useful in the present invention and thus have not described this genus in a manner that would allow one skilled in the art to immediately envisage the compositions contemplated for use in the claimed methods. As such, the claims lack adequate written description for the claimed composition for administration other than those compositions described in claim 16 and at page 12 of the instant specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 13-16, 23-27, 29 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Moulinoux et al. (CA 2165481, which is the English language equivalent of WO 95/00041, as per Applicant's IDS).

Moulinoux et al. teach a composition that can be ingested by man which contains less than about 1600 picomoles/g of polyamine (p. 5, lines 15-17). More specifically this composition which can be administered to man preferably contains less than about 50 picomoles/g of putrescine, spermidine, spermine and cadaverine respectively (p. 5, lines 27-34). The composition which is to be administered further comprises 10-35% lipids, 8-30% proteins, 35-80% glucides and up to 10% of a mixture composed of vitamins, minerals and electrolytes as a percentage of dry weight with respect to the total composition (p. 6, lines 5-10). More specifically, the preferred glucides are glucose polymers, maltodextrines, saccharose, modified starches, monohydrated glucose, dehydrated glucose syrup, glycerol monostearate and mixtures of these substances (p. 9, lines 27-31). The preferred proteins are soluble milk proteins, soya proteins, serum peptides, powdered egg yolk, potassium caseinate, unphosphorylated peptides, casein peptides, mixed caseinate, soya isolate and mixtures of these substances (p. 10, lines 1-6). The preferred lipids are butter oil, peanut oil, medium chain triglycerides, grape pip oil, soya oil, onager oil and mixtures of these oils and the lipids are advantageously composed of a mixture of at least one animal oil, at least one vegetable oil and glycerol stearate (p. 10, lines 7-12). With respect to claims 31-32, the composition to be administered may be in dry form to be dissolved extemporaneously in a neutral vehicle suitable for oral or enteral administration (p. 6, lines 11-14).

With respect to claim 27, Moulinoux et al. teach that the composition to be administered forms a daily food ration for one person and includes

- between 75 g and 500 g of glucides,

- between 20 g and 185 g of lipids,

- between 20 g and 225 g of proteins,

- sufficient quantities of vitamins, minerals and electrolytes to satisfy the daily nutritional needs of a human being (p. 10, lines 15-24). This composition is taught to reduce intracellular synthesis and external input of polyamines (p. 10, lines 32-35).

With respect to claim 29, Moulinoux et al. teach that the composition can be administered several times per day and this composition includes

- between 75/~g and 500/~g of glucides,

- between 20/X g and 185/X g of lipids,

- between 20/~g and 225/~g of proteins,

- sufficient quantities of vitamins, minerals and electrolytes to partially satisfy the daily nutritional needs of a human being, where X is an integer between 2 and 8, equal to the number of rations to be ingested by the patient to satisfy his daily nutritional needs (p. 11, lines 9-17). Examples 1 and 2 are directed to specific polyamine deficient composition.

When the above polyamine deficient compositions are administered to man, it is known to induce a powerful antalgic effect (p. 13, lines 1-4). The antalgic or pain killing effect of the polyamine deficient compositions is demonstrated in the examples beginning at page 21 and continuing though page 23. Please note that the

compositions and experiments showing the antalgic effect of these compositions as taught by Moulinoux et al. are identical to those of the instant specification. As evidenced by the instant specification, pain is a condition in which the NR2-B subunit of the N-methyl-D-aspartate is involved. See page 1, lines 8-15). Because Moulinoux et al. teaches administering compositions identical to those instantly claimed to humans (i.e. the required active step of the claims), for the same purpose, the claims are anticipated.

## ***Conclusion***

Claims 1, 13-16, 23-27, 29 and 31-32 are rejected. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Ashwin Mehta/

Primary Examiner, Technology Center 1600